



Office de la propriété  
intellectuelle  
du Canada

Un organisme  
d'Industrie Canada

Canadian  
Intellectual Property  
Office

An Agency of  
Industry Canada

PCT/CA 2004/000714

07

JUNE

2004 07.06.04

REC'D 07 JUL 2004

WIPO

PCT

Bureau canadien  
des brevets  
Certification

La présente atteste que les documents ci-joints, dont la liste figure ci-dessous, sont des copies authentiques des documents déposés au Bureau des brevets.

Canadian Patent  
Office  
Certification

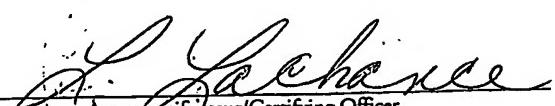
This is to certify that the documents attached hereto and identified below are true copies of the documents on file in the Patent Office.

Specification and Drawings, as originally filed, with Application for Patent Serial No: 2,428,741, on May 13, 2003, by CARDIANOVE INC., assignee of Michel Carrier, André Garon, Ricardo Camarero, Conrad Pelletier et Victor Obeid, for "Dual Inlet Mixed-Flow Blood Pump".

BEST AVAILABLE COPY

**PRIORITY  
DOCUMENT**

SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH RULE 17.1(a) OR (b)

  
Agent/Certificateur/Certifying Officer

June 7, 2004

Date

(CIPO 68)  
04-09-02

Canada

OPIC  CIPO

**TITLE OF THE INVENTION**

DUAL INLET MIXED-FLOW BLOOD PUMP

**5    FIELD OF THE INVENTION**

The present invention relates to a mixed-flow blood pump displaying characteristics of both radial-flow and axial-flow pumps.

**10    BACKGROUND OF THE INVENTION**

In North America, heart related diseases are still the leading cause of death. Among the causes of heart mortality are congestive heart failure, cardiomyopathy and cardiogenic shock.

15    The incidence of congestive heart failure increases dramatically for people over 45 years of age. In addition, a large part of the population in North America is now entering this age group. Thus, patients who will need treatment for these types of diseases comprise a larger segment of the population. Many complications related to congestive heart failure, 20    including death, could be avoided and many years added to these patients' lives if proper treatments were available.

25    The types of treatments available for patients of heart failure depend on the extent and severity of the illness. Many patients can be cured with rest and drug therapy but there are still severe cases that require various heart surgeries, including heart transplantation. Actually, the mortality rate for patients with cardiomyopathy who receive drug therapy is about 25% within two years and there still is some form of these diseases that cannot 30    be treated medically. One of the last options that remain for these patients is heart transplantation. Unfortunately, according to the procurement

agency UNOS (United Network for Organ Sharing in the United States), the waiting list for heart transplantation grows at a rate of more than twice the number of heart donors.

- 5 Considering the above facts, it appears imperative to offer alternative treatments to heart transplantation. The treatment should not only add to a patient's longevity but also improve his quality of life. In this context, mechanical circulatory support through Ventricular Assist Devices (VAD) is a worthwhile alternative given the large deficiency in the number of 10 available organ donors. It is estimated that eight thousand (8,000) patients per year in Canada and seventy-six thousand patients (76,000) per year in the United States could benefit from VADs.

- 15 In 1980, the National Heart, Lung and Blood Institute (NHLBI) of the United States defined the characteristics for an implantable VAD (Altieri, F.O. and Watson, J.T. 1987, "Implantable Ventricular Assist Systems", *Artif Organs*, Vol. 11, pp. 237-246). These characteristics include medical requirements including restoration of hemodynamic function (pressure and cardiac index) avoidance of hemolysis, prevention of clot formation, infection and 20 bleeding, and minimisation of the anti-coagulation requirement. Further technical requirements include: small size, control mode, long life span (> 2 years), low heating, noise and vibration.

- 25 Several VADs have been developed to enhance blood circulation and reduce the load on the heart of patients having poor hemodynamic functions (low cardiac output, low ejection fraction, low systolic pressure). These VADs include pulsatile VADs, and non-pulsatile VADs such as radial-flow blood pumps and axial-flow blood pumps.

- 30 Pulsatile VADs were developed to imitate as much as possible the heart physiology. This resulted in the development of a first generation of

pneumatically driven pulsatile VADs and a second generation of electrically actuated pulsatile VADs. A first problem is that operation of pulsatile VADs requires high energy consumption. Another problem is that their large size does not allow pulsatile VADs to be easily implanted in the human body.

5

Non-pulsatile VADs comprise an impeller enclosed in a housing and continuously rotating to produce a pumping action. The faster the rotation, the higher the blood flow. These VADs are called non-pulsatile or continuous VADs because they provide for a constant blood flow. Many advantages are associated with the use of non-pulsatile VADs. These advantages include:

- Non-pulsatile VADs require a much smaller volume than pulsatile VADs to facilitate implantation thereof in the human body;

15

- The electrical power required to drive a non-pulsatile VAD is lower than for pulsatile VADs;

20

- Non-pulsatile VADs are mechanically simpler than pulsatile VADs; they do not require complex structures such as valves, diaphragms, blood sacs, vents or compliance chambers. One important advantage of a simpler mechanical design is an extended durability, which will allow not only to use a non-pulsatile VAD as a bridge to transplantation but also as medium and long term mechanical cardiac support;

25

- The probability of infection is reduced with non-pulsatile VADs. This is due in large part to the fact that pulsatile VADs require a transcutaneous vent constituting an open door for opportunist infections; and

30

- 5
- Non-pulsatile VADs require less maintenance allowing the patient a greater autonomy. Also, most patients with a non-pulsatile VAD are discharged from the hospital and returned to a normal life after about a month. Presently, because of the vent in pulsatile VADs, patients cannot take a bath or swim since water could enter the motor compartment. Non-pulsatile VADs are less restrictive and allow the patient to practice more activities.

10 A first example of non-pulsative VADs are radial-flow blood pumps. In radial-flow blood pumps, the rotation of the impeller produces a centrifugal force that drags blood from the inlet port on top to the outlet port at the bottom. A problem related to radial-flow blood pumps is that although they are much smaller than pulsatile VADs, they are still too large to be totally implanted in a human thorax thus eliminating any intra-ventricular  
15 implantation.

20 To overcome the above-mentioned problem related to radial-flow blood pumps, axial-flow blood pumps were developed. These axial-flow blood pumps can decrease the hemolysis rate by decreasing the time of exposure of the blood to friction forces and by reducing the intensity of these forces. Another interesting advantage is that axial-flow blood pumps are generally much smaller than radial-flow blood pumps, and can be much more easily implanted in the human body, even in the left ventricle of the heart, for medium and long term mechanical cardiac support.

25 Many of the above-described VADs can achieve the goals of restoring the hemodynamic functions and improving end organ perfusion. However both power efficiency and pumping efficiency of these VADs can still be improved, and hemolysis and thrombus formation are still important  
30 problems requiring investigation.

**SUMMARY OF THE INVENTION**

The present invention relates to an improved mixed-flow blood pump presenting features of both axial-flow and radial-flow pumps.

- 5 This mixed-flow blood pump comprises a stationary housing structure and a rotative impeller. The stationary housing structure defines at least one blood inlet, a blood outlet, and a blood conduit between these blood inlet and blood outlet, and the rotative impeller is mounted in the blood conduit.
- 10 The foregoing and other objects, advantages and features of the present invention will become more apparent upon reading of the following non-restrictive description of illustrative embodiments thereof, given by way of example only with reference to the accompanying drawings.
- 15

**BRIEF DESCRIPTION OF THE DRAWINGS**

In the appended drawings:

- 20 Figure 1 is a cross sectional view of a human heart in which an illustrative intra-ventricular embodiment of the mixed-flow blood pump according to the present invention is implanted;
- 25 Figure 2 is a graph showing, for different types of pumps, a curve relating a specific pump rotation speed  $N_s$  with a specific pump diameter  $D_s$  at the points where the pump is operating at maximum hydraulic efficiency;
- 30 Figure 3 is a side elevational and cross sectional view of an illustrative intra-ventricular embodiment of the mixed-flow blood pump according to the present invention;

Figure 4 is a front elevational view of a frusto-conical inflow bushing of the embodiment of Figure 3, showing the configuration of the inner surface of this bushing;

5 Figure 5 is a front elevational view of a frusto-conical outflow bushing of the embodiment of Figure 3, showing the configuration of the inner surface of this bushing;

10 Figure 6 is a side elevational and cross sectional view of an illustrative extra-ventricular embodiment of the mixed-flow blood pump according to the present invention; and

15 Figure 7 is a schematic view of an illustrative embodiment of a VAD system implanted in a human being and comprising the mixed-flow blood pump of Figure 3.

#### DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS

It should first be mentioned that the mixed-flow blood pump according to the present invention can be used as part of:

- 20
- an intra-corporal system such as an intra-ventricular VAD;
  - an extra ventricular VAD (for example a VAD located in the abdomen or thorax); or
  - as a para-corporal or extra-corporal VAD (for example in a bridge to heart transplantation).

25 It should also be understood that the mixed-flow blood pump of the present invention can be used either in temporary VADs (for example a bridge to heart transplantation), or medium and long term VADs.

30 Figure 1 illustrates a possible position for an illustrative, intra-ventricular embodiment 10 of mixed-flow blood pump according to the present

invention in the left ventricle 11 of a patient's heart 12.

The illustrative, intra-ventricular embodiment 10 of mixed-flow blood pump according to the present invention has been designed and dimensioned to fit in small adults and in teens. Since the physical size and shape of the mixed-flow blood pump 10 are greatly influenced by the size and shape of the left ventricle 11, a thorough description of the anatomy of the left ventricle of the human heart is required. Feigenbaum, Harvey, "Echocardiography", 5th Edition, 1994, Lea & Febiger, Philadelphia, presents several dimensions of the human heart normalized by the BSA (Body Surface Area). These anatomical dimensions have been statistically determined and are known to represent 95% of the population. Taking into consideration the above statistics, a ventricular dimension for human adults and teens corresponding to a BSA of  $1.5 \text{ m}^2$  was used to design the illustrative, intra-ventricular embodiment 10 of mixed-flow blood pump according to the present invention.

It will be understood that the size and shape of the illustrative intra-ventricular embodiment of the mixed-flow blood pump 10 according to the present invention could also be adapted to meet the anatomical dimensions of individuals falling outside this 95% of the population. Similarly, the size and shape could be adapted to specific and particular individuals and heart conditions.

For 95% of the population, the internal diameter of the left ventricle 11 ranges from 37 to 46 mm in diastole and between 22 to 31 mm in systole. This diameter is determined at the centre of the ventricular length (segment AB in Figure 1). The diameter near the apex at the first third of the ventricular length is about 15 mm (segment CD of Figure 1). The internal length of the ventricle from the apex to the aortic valve ranges from 55 to 70 mm. Finally, the other important parameter is the surface of the

aortic valve opening, which ranges from 2.5 to 4 cm<sup>2</sup>.

- Obviously, the external design (shape and size) of the illustrative intra-ventricular embodiment of the mixed-flow blood pump 10 according to the present invention (Figure 1) will depend on the above anatomic dimensions of the left ventricle 11. Figure 3 illustrates the external outline of the illustrative intra-ventricular embodiment of the mixed-flow blood pump 10 according to the present invention. The diameter of the mixed-flow blood pump 10 is a compromise between pumping requirements and minimal interference with heart contraction. In the illustrative intra-ventricular embodiment 10 of mixed-flow blood pump according to the present invention, the maximum allowable diameter 13 is about 22 mm, which is the diameter of the left ventricle 11 in systole. This dimension is reasonable since people with heart failure generally have dilated ventricles.
- The maximum length of the illustrative intra-ventricular embodiment 10 of mixed-flow blood pump according to the present invention, as illustrated in Figure 3, is set in regard of the average distance between the apex 14 and the aortic valve 15 of the heart 12. The length 16 of the illustrative intra-ventricular embodiment of the mixed-flow blood pump 10 according to the present invention is about 65 mm. As shown in Figure 3, a reduction of the pump diameter (see 17) toward the outflow increases the aortic valve clearance in order to minimise interference with the aortic valve function.
- Since this illustrative intra-ventricular embodiment of the mixed-flow blood pump 10 will be completely located inside the left ventricle 11, blood will circulate around the pump 10. As a consequence, all external surfaces of the pump 10 should be as smooth as possible and avoid as much as possible abrupt deviations to thereby minimise recirculation and stagnation zones which may be at the origin of clot formation. To overcome this problem, the illustrative intra-ventricular embodiment of the mixed-flow

blood pump 10 according to the present invention and other components may be machined from surgical quality titanium.

From a surgical point of view, a non-limitative illustrative procedure for  
5 inserting the illustrative intra-ventricular embodiment 10 of mixed-flow blood pump is to use the same approach as with valve replacement. According to this procedure, an incision is made at the root of the aorta 18 (Figure 1) and the mixed-flow blood pump 10 is inserted through the aortic valve and then into the left ventricle 11. The mixed-flow blood pump 10 is  
10 then pushed until its base reaches the myocardium at the apex 14.

To prevent motion thereof, the illustrative, intra-ventricular embodiment of mixed-flow blood pump 10 is finally fixed by means of a fixation mechanism 19 provided at a first end of the pump 10 (Figure 3). As an  
15 example, fixation mechanism 19 comprises:

- an elongated hollow needle member 20 extending from the first end of the pump 10, this needle member 20 being driven from the inside of the left ventricle 11 through the myocardium and the epicardium  
20 at the apex 14 of the heart 12; and
- a fixation disk 21 fastened to the free end of the needle member 20 on the outside of the heart 12 to firmly fix the mixed-flow blood pump 10 within the left ventricle 11.

25 Of course, it is within the scope of the present invention to employ any other type of fixation mechanism.

Since one of the main functions of the illustrative intra-ventricular embodiment 10 of mixed-flow blood pump is to restore the hemodynamic  
30 function in patients with cardiac failure, and depending on the severity of

the failure and the BSA, the pump 10 is susceptible to work at flow rates between 2 to 6 litres per minute (l/min) against a pressure as high as 120 mmHg and, more commonly, at a flow rate between 3 to 5 l/min against a pressure of 80 mmHg. A high efficiency pump design is therefore required.

- 5 There are three existing non-pulsatile pump configurations, all turbines, and having characteristics which make them potential candidates for a high efficiency cardiac support blood pump: radial-flow, axial-flow and mixed-flow pumps. Given their relatively small diameter, cylindrical shape and high throughput, axial-flow pumps display a number of characteristics that make them particularly well suited for implantation. However, other pump configurations also exhibit characteristics, different from those of the axial-flow pump, which would also be useful in a cardiac support blood pump.
- 10
- 15 When designing turbine pumps, dimensionless characteristic values are used to compare different pump configurations. Dimensionless characteristic values provide useful indications to pump designers of expected performance regardless of the size of the pump, a comparison which would otherwise prove difficult given a virtually infinite number of operating parameters that depend on infinite variations of internal pump geometry. These dimensionless characteristic values, therefore, can be used to provide an objective starting point for the selection of a general pump configuration.
- 20
- 25 Two of these dimensionless characteristic values are the specific rotation speed  $N_s$  of the pump and the specific pump diameter  $D_s$ . They are defined as follows:

$$N_s = \frac{\Omega Q^{1/2}}{H^{3/4}} \quad (1)$$

$$D_s = \frac{D \cdot H^{1/4}}{Q^{1/2}} \quad (2)$$

5 where  $\Omega$  is the speed of rotation of the pump 10 in radians/second,  $Q$  is the flow rate in  $m^3/\text{second}$ ,  $H$  is the head (i.e. the gain in pressure) of the pump 10 and  $D$  the diameter of the pump, both in meters.  $N_s$  remains the same regardless of the size of the pump and therefore provides an accurate measure of the performance of a given pump design.  $D_s$  relates the pump diameter to the pump head  $H$  and flow rate  $Q$ .

10 Referring to Figure 2, the design curve relates the specific speed  $N_s$  with the specific diameter  $D_s$  to yield the optimal pump configuration. Specifically, if the configuration of  $N_s$  and  $D_s$  falls on the curve, the maximum hydraulic efficiency of the design is greater than if it falls away 15 from the curve. In this regard, hydraulic efficiency is expressed as the percentage of the power input to the pump which is converted to energy of movement of the fluid within the pump. From the curve of Figure 2 and equation (1) above, it follows that optimally efficient pumps having a higher specific speed also have a smaller size.

20 As referred to above, there are three (3) principal categories of non-pulsatile pumps characterised by the direction of the flow of fluid through the pump relative to the axis of rotation: axial-flow, radial-flow and mixed-flow pumps [Wright, Terry, "Fluid Machinery: Performance Analysis and 25 Design", 1999, CRC Press].

In axial-flow pumps the direction of fluid flow is parallel to the axis of rotation. The pressure differential, or head, is produced by a change in the amount of tangential movement. Characteristics associated with axial-flow 30 pumps include high flow rate  $Q$  and small head  $H$ . This results in high

~~specific~~ speeds  $N_s$ . Therefore the range of specific speed and diameter for radial-flow pumps is  $1.8 < N_s < 3.0$  and  $1.65 < D_s < 2.2$ , as illustrated on Figure 2.

- 5 In radial-flow pumps a large portion of the throughput, either on the outlet or ~~the~~ inlet, is radial, i.e. perpendicular to the axis of rotation. This change in direction causes an increase in pressure. Contrary to an axial-flow pump, a radial-flow pump is characterised by relatively large head  $H$  and smaller flow rate  $Q$ , resulting in lower specific speeds  $N_s$ . Therefore the 10 range of specific speed and diameter for radial-flow pumps is  $0.7 < N_s < 1.0$  and  $2.8 < D_s < 4.0$ , as illustrated on Figure 2.

Located between radial-flow pumps and axial-flow pumps are mixed-flow pumps where the direction of flow at the outlet or inlet is composed of both 15 radial-flow and axial-flow components. As would be expected, the specific speed of mixed-flow pumps is located between the specific speeds of axial-flow and radial-flow pumps. Therefore the range of specific speed and diameter for mixed-flow pumps is  $1.0 < N_s < 1.8$  and  $2.2 < D_s < 2.8$ , as illustrated in Figure 2.

- 20 In order to determine an optimised choice for a pump, it is necessary to evaluate the specific speed  $N_s$  in light of the characteristics in terms of head  $H$  and flow rate  $Q$  projected for the pump. As discussed above, the pump will typically be operated with a flow rate of 5 litres/minutes and a 25 head of approximately 100 mmHg. Additionally, current motor technology provides small yet efficient motors operating at a speed of 7,500 RPM. This gives a specific speed of 1.12 and a specific diameter of 2.45 for a maximum internal diameter of 12 mm.
- 30 Referring again to Figure 2, an indication is given to the ranges of  $N_s$  and  $D_s$  within which a given pump configuration will provide efficient operation.

The specific speed  $N_s$  of 1.12 falls within a transition region of the curve between axial-flow and radial-flow pumps. In this transition region, a mixed-flow pump topology would yield a higher efficiency than purely radial-flow or axial-flow pumps. Additionally, the specific diameter  $D_s$  is 5 around 2.45 which, by applying Equation (2) above, yields a maximum impeller drive shaft 63 diameter of 12 mm, i.e. a very small pump. Accordingly, a mixed-flow pump design has been selected.

10 The structure and operation of the illustrative intra-ventricular embodiment of the mixed-flow blood pump 10 according to the present invention will now be described.

15 Referring to Figure 1, the illustrative intra-ventricular embodiment of the mixed-flow blood pump 10 according to the present invention rests at the bottom of the left ventricle 11, in the region of the apex 14 of the heart 12.

As shown in Figures 1 and 3, in order to prevent the inner walls of the left ventricle 11 from completely obstructing blood intake, the illustrative intra-ventricular embodiment 10 of mixed-flow blood pump comprises a 20 stationary housing structure 100 including two axially spaced apart, annular radial-flow inlets 22 and 23. Additionally, the proximal end of the stationary housing structure 100 presents a surface 24 presenting the general configuration of a hemisphere. The diameter of the hemisphere is set to approximately 20 mm, which is smaller than the segment CD (see 25 Figure 1) and suitable to limit the level of pressure on the walls of the left ventricle 11 near the apex 14.

30 The stationary housing structure 100 of the illustrative intra-ventricular embodiment 10 of mixed-flow blood pump according to the present invention comprises a hollow cylindrical member 25 containing the stator windings such as 26 and the associated magnetic cores such as 27. The

hollow cylindrical member 25 is made of two mutually mating annular pieces 28 and 29 connected together. This will allow insertion of the stator windings 26 and cores 27 within the hollow cylindrical member 25.

- 5    The stationary housing structure further comprises an inflow bushing mount 30 mounted on a proximal end of the cylindrical member 25. More specifically, the bushing mount comprises an annular portion 31 profiled to fit on the proximal end of the hollow cylindrical member 25 while defining with this cylindrical member 25 a smooth surface for the annular radial-flow inlet 22. The bushing mount 30 also comprises a wall 32 presenting the general configuration of a hemisphere. The outer face of the hemispheric wall 32 defines the above-mentioned hemispheric surface 24. The inner face of the hemispheric wall 32 is connected to the annular portion 31 through a series of radial blades such as 33 and 34 spread out evenly around a longitudinal axis 41 of the pump 10, within the radial-flow inlet 22.
- 10   Another function of the blades such as 33 and 34 is to straighten out the flow of blood through the radial-flow inlet 22. An inflow bushing 35 having the general configuration of a frustum of cone is mounted inside the annular portion 31 of the bushing mount 30 and is centered on the longitudinal axis 41 of the blood pump 10. More specifically, the frusto-conical bushing 35 is mounted to the annular portion 31 through a series of radial blades such as 36 and 37 spread out evenly around the axis of the pump, more specifically around the frusto-conical bushing 35. As illustrated in Figure 3, the frusto-conical bushing 35 has an end of larger diameter facing toward the distal end of the pump 10. Again, another function of the blades such as 36 and 37 is to straighten out the flow of blood passing between the frusto-conical bushing 35 and the annular portion 31 of the bushing mount 30.
- 15
- 20
- 25
- 30   The stationary housing structure 100 of the illustrative intra-ventricular embodiment 10 of mixed-flow blood pump according to the present

invention further comprises an impeller housing 38.

The proximal end of this impeller housing 38 is connected to the distal end of the cylindrical member 25 through a series of radial blades such as 39 and 40 spread out evenly around the longitudinal axis 41 to define the second annular radial-flow inlet 23 between the distal end of the cylindrical member 25 and the proximal end of the impeller housing 22. Another function of the radial blades such as 39 and 40 is to straighten out the flow of blood through the annular radial-flow inlet 23.

As mentioned hereinabove, the first annular radial-flow inlet 22 is axially spaced apart from the second annular radial-flow inlet 23 to reduce as much as possible the effect occlusion of one of the inlets 22 or 23 may have on normal operation of the blood pump 10.

Referring to Figures 1 and 3, the outer diameter of the impeller housing 38 reduces from the proximal end to the distal end of this impeller housing 38 so as to form an outflow cannula 42 and reduce as much as possible the obstruction caused to the operation of the aortic valve (not shown); since the function of the mixed-flow blood pump 10 is to assist blood circulation, blood flow contribution from the natural contraction of the heart 12 should be maintained. In the illustrative intra-ventricular embodiment 10 of mixed-flow blood pump according to the present invention, the area of the outflow cannula 42, corresponding to diameter 43, is  $1.0 \text{ cm}^2$ .

As illustrated in Figure 3, the outflow cannula 42 of the illustrative intra-ventricular embodiment 10 of mixed-flow blood pump according to the present invention is integral with the impeller housing 38.

A blood diffuser 32 (not shown) can be mounted at the free end of the outflow cannula 42 (distal end of the impeller housing 38). The function of

- this blood diffuser would be to reduce the shear stress on blood cells. Without diffuser, the velocity of blood ejected from the pump 10 is higher than the velocity of blood ejected from the heart 12. The difference in velocity between these two blood flows would result in shear stress
- 5 proportional to this difference. Since the velocity is inversely proportional to the cross-sectional area, a solution for reducing the relative velocity of the blood flows from the pump 10 and from the heart 12 is (a) to increase the area of the orifice 44 of the cannula 42 to reduce the velocity of the flow of blood from the pump 10, and (b) to decrease the area occupied by the
- 10 blood flow from the heart 12 to increase the velocity of the latter blood flow. This would be exactly the role of the blood diffuser. Of course, parameters such as the angle of opening and the length of the blood diffuser could be adjusted at will to fit the mechanical characteristics of the pump 10 in view of minimising the shear stress on the blood cells.
- 15 The impeller housing 38 comprises an outflow stator 45 formed of a series of inner radial blades spread out evenly around the longitudinal axis 41. The radial blades are configured to straighten out the flow of blood exiting the cannula 42 and are held in place by the impeller housing 38.
- 20 An outflow bushing 46 having the general configuration of a frustum of cone is mounted inside the outflow stator 45 and is centered on the longitudinal axis 41. More specifically, the frusto-conical bushing 46 is mounted to the radial blades of the outflow stator 45. Finally, the end of
- 25 larger diameter of the frusto-conical bushing 46 is facing toward the proximal end of the pump 10.
- The illustrative, intra-ventricular embodiment 10 of mixed-flow blood pump also comprises a rotative impeller 56 provided with an impeller drive shaft
- 30 55 centered on the longitudinal axis 41. The impeller drive shaft 55 comprises an inflow end portion 57 formed with a frusto-conical face 58

structured to snugly fit into the frusto-conical bushing 35.

Figure 4 illustrates the inner face 47 of the inflow bushing 35. Inner face 47 comprises three axial grooves 48, 49 and 50 evenly spread out around the longitudinal axis 41. From groove 48 to groove 49, the inner face 47 defines a pad 51 and a land 52. In the same manner, from groove 49 to groove 50, the inner face 47 defines a pad 53 and a land 59. Finally, from groove 50 to groove 48, the inner face 47 defines a pad 60 and a land 61. Pad 51 has a diameter that gradually increases from groove 48 to land 52. Pad 53 has a diameter that gradually increases from groove 49 to land 59. Pad 60 has a diameter that gradually increases from groove 50 to land 61. Lands 52, 59 and 61 have the same constant diameter.

In operation, the lands 52, 59 and 61 form a seat for the frusto-conical face 58 of the inflow end portion of the impeller drive shaft 55. The grooves 48, 49 and 50 enable flow of blood between the faces 47 and 58. The hydrodynamic forces produced by rotation of the impeller drive shaft 55 will produce a thicker film of blood flowing between the frusto-conical face 58 of the inflow end portion 57 of the impeller drive shaft 55 and the pads 51, 53 and 60, and a thinner film of blood flowing between face 58 and the lands 52, 59 and 61 to thereby lubricate the resulting bearing (frusto-conical face 58 and frusto-conical bushing 35). A taper such as 62 is formed in the edge of larger diameter in the region of the pads and lands. Since blood flows through the gap between the frusto-conical faces 47 and 58, minimal hemolysis, thrombus and clot formation will be produced.

More specifically, the resulting inflow bearing (frusto-conical face 58 and frusto-conical bushing 35) has the following characteristics:

- Maximum diameter: 8 mm
- Minimum diameter: 3 mm
- Cone angle: 20°

- 5
- Axial length: 6.87 mm
  - Taper cone length: 7.31 mm
  - Number of pads: 3
  - Pad angle about the longitudinal axis: 100°
  - Groove angle about the longitudinal axis: 20°
  - Taper angle: 82.5°
  - Taper height: 0.02-0.04 mm
  - Land angle about the longitudinal axis.

10

INFLOW 7000 RPM						
C=Clearance (mm)	Radial Gap (mm)	Axial Gap (mm)	Axial Load (N)	Minimum Film (mm)	Power Loss (Watt)	Maximum Pressure (Pa)
0.0103	0.0109	0.0300	1.26	0.0103	0.14	97180

WITH A 0.8 N MAGNETIC PULL AXIALLY

15 Referring back to Figure 3, the impeller drive shaft 55 also comprises an outflow portion 63 which, when assembled to the inflow end portion 57 defines a cavity in which a permanent magnet 64 is inserted. The windings 26 and the permanent magnet 64 form an electric motor structure operative to set the impeller 56 into rotation; the magnetic field produced by the windings 26 is applied to the magnetic field produced by the permanent magnet 64 to produce a reaction that will set the impeller 56 into rotation.

20

The above-mentioned 0.8 N axial magnetic pull is produced by slightly offsetting the permanent magnet 64 toward the inflow bushing 35 with

respect of the magnetic windings 26. This will produce the 0.8 N axial magnetic pull toward the outflow bushing 46, i.e. in a direction opposite to an axial force produced on the impeller drive shaft 63 upon pumping blood.

- 5 An axial screw 65 passes through the magnet 64 and screws into both the inflow 57 and outflow 63 portions of the impeller drive shaft 55 to firmly secure these two drive shaft portions together.

- 10 The outflow portion 63 of the impeller drive shaft 55 comprises an outflow end 66 formed with a frusto-conical face 67 structured to snugly fit into the frusto-conical bushing 46.

- 15 Figure 5 illustrates the inner face 68 of the outflow bushing 46. Inner face 68 comprises three axial grooves 69, 70 and 71 evenly spread out around the longitudinal axis 41. From groove 69 to groove 70, the inner face 68 defines a pad 72 and a land 73. In the same manner, from groove 70 to groove 71, the inner face 68 defines a pad 74 and a land 75. Finally, from groove 71 to groove 69, the inner face 68 defines a pad 76 and a land 77. Pad 72 has a diameter that gradually increases from groove 69 to land 73.  
20 Pad 74 has a diameter that gradually increases from groove 70 to land 75. Pad 76 has a diameter that gradually increases from groove 71 to land 77. Lands 73, 75 and 77 have the same constant diameter.

- 25 In operation, the lands 73, 75 and 77 form a seat for the frusto-conical face 67 of the outflow portion 63 of the impeller drive shaft 55. The grooves 69, 70 and 71 enable flow of blood between the faces 67 and 68. The hydrodynamic forces produced by rotation of the impeller drive shaft 55 will produce a thicker film of blood flowing between the frusto-conical face 67 of the outflow portion 63 of the impeller drive shaft 55, and the pads 72, 74 and 76, and a thinner film of blood flowing between face 67 and the lands 30 73, 75 and 77 to thereby lubricate the resulting bearing (frusto-conical face

67 and frusto-conical bushing 46). A taper such as 78 is formed in the edge of larger diameter in the region of the pads and lands. Since blood flows through the gap between the frusto-conical faces 67 and 68, minimal hemolysis, thrombus and clot formation will be produced.

5

As an example, the resulting outflow bearing (frusto-conical face 67 and frusto-conical bushing 46) may have the following characteristics:

- Maximum diameter: 6 mm
- Minimum diameter: 3 mm
- 10 - Cone angle: 20°
- Axial length: 4.1212 mm
- Taper cone length: 4.3857 mm
- Number of pads: 3
- Pad angle about the longitudinal axis: 100°
- 15 - Groove angle about the longitudinal axis: 20°
- Taper angle: 80°
- Taper height: 0.02-0.03 mm
- Land angle about the longitudinal axis: 20°

20

OUTFLOW 7000 RPM						
Clearance (mm)	Radial Gap (mm)	Axial Gap (mm)	Axial Load (N)	Minimum Film (mm)	Power Loss (Watt)	Maximum Pressure (Pa)
0.0157	0.0167	0.0460	0.16	0.0157	0.03	22895

WITH THE ABOVE MENTIONED 0.8 N MAGNETIC PULL AXIALLY

In the illustrative embodiment of Figure 3, the impeller 56 comprises a set

of impeller blades such as 78 and 79 evenly distributed around a tapered section 80 of the outflow portion of the impeller drive shaft 55 situated inside the impeller housing. It should be noted here that the annual radial-flow inlet 23 leads to the proximal end of the impeller blades such as 78 and 79. The shape (curvature and angulation) of the impeller blades such as 78 and 79 should be optimally designed in relation to pumping performance and other hydrodynamic considerations. In particular, the influence of the blade angulation on the level of shearing stresses, turbulence and cavitation responsible for red blood cell damage and increase of hemolysis rate must be carefully taken into consideration.

In the approach proposed by the illustrative intra-ventricular embodiment of the present invention, the mixed-flow blood pump 10 presents an enclosed-impeller mixed-flow configuration. The impeller section 80 of the impeller drive shaft 55 bearing the impeller blades such as 78 and 79 is tapered in the direction opposite to the direction of blood flow. This contributes to create the mixed-flow operation of the blood pump 10. More specifically, this taper imparts to the blood flow both axial and radial components.

For housing the impeller blades, the impeller housing 38 comprises an inner surface 81 slightly less tapered in the direction opposite to the direction of blood flow than the section 80. To fit in the annular space defined between tapered section 80 and the tapered surface 81, the width of the impeller blades such as 78 and 79 slightly and gradually decreases in the direction of blood flow. This also contributes to impart to the blood flow both axial and radial components.

The end section 82 of the outflow portion 63 of the impeller drive shaft 55 is tapered in the direction of blood flow to fit within the outflow stator 45 and define the frusto-conical face 67. The inner surface 83 of the impeller

housing surrounding the end section 82 and the outflow stator 45 is slightly less tapered in the direction of blood flow than the end section 82 of the impeller drive shaft 55. To fit in the annular space between the inner tapered surface 83 and the end section 82, the radial blades such as 45  
5 has a height that slightly and gradually increases in the direction of blood flow.

The required electrical supply for the stator windings 26 is made through electrical wires extending through a conduit 84 itself extending from the  
10 cavity in which the stator windings 26 are installed through the annular portion 31, the radial blade 33, the hemispheric wall 32, and the hollow needle 20 to reach a controller and an energy source (both to be described hereinafter). Of course, this conduit 84 is sealed prior to implantation of the pump 10 within a human body.

15 Electric supply of the stator windings 26 will cause rotation of the impeller drive shaft and therefore rotation of the set of impeller blades such as 78 and 79. More specifically, in the illustrative embodiment of Figure 3, the mixed-flow blood pump 10 is actuated by means of a brushless DC (direct current) motor formed by the stator windings 26 housed in the cylindrical member 25 and the permanent magnet 64 embedded or housed in the impeller drive shaft 55. This brushless configuration presents the advantage of minimal wear. Two other interesting characteristics of brushless DC motors are high rotational speed and high torque.  
20

25 As discussed in the following description, the cylindrical gap 86 between the outer surface of the impeller drive shaft 55 and the inner surface of the cylindrical member 25 must be sufficiently thick to produce sufficient blood flow in order to increase washout and prevent clot formation. However,  
30 increasing the thickness of the gap 86 decreases the efficiency of the magnetic coupling between the permanent magnet 64 and the stator

windings 26. This requires an increase in current through the stator windings 26 to compensate for the decreased efficiency and to maintain the same characteristics in terms of impeller blade speed and blood volume throughput. Of course, increase in current leads to an increase in thermal loss from the stator windings 26; this thermal loss increases as the square of the current through the stator windings 26. As the temperature of the surface of the stator windings must remain at or below 40°C, the gap 86 must be sufficiently small to provide efficient magnetic coupling between the permanent magnet 64 and the stator windings 26.

Thermal performance is also improved given the proximate position of the stator windings 26 to the external surface 92 of the cylindrical member 25. Blood flow over the external surface 82 efficiently cools the stator windings 26. The flow of blood within the gap 86 also contributes in efficiently cooling the stator windings 26.

Axial spacing between the impeller blades such as 78 and 79 and the permanent magnet 64 along the impeller shaft enables separate design of the motor and the impeller blades to obtain simultaneously both efficient coupling between the permanent magnet and the stator windings and sufficient pumping volume.

Rotation of the impeller blades such as 78 and 79 will impart pumping energy to the blood within the annular space between the tapered section 80 of the drive shaft 55 and the tapered inner surface 81 of the impeller housing. This will cause sucking of blood both through the annular radial-flow inlets 22 and 23. More specifically:

- Blood flow enters the annular radial-flow inlet 22, is straightened out by the radial blades such as 33 and 34, fills the proximal chamber 85 with blood, is again straightened out by the radial blades such as

36 and 37 and is finally conducted toward the impeller blades such as 78 and 79 through the cylindrical gap 86 between the impeller drive shaft 55 and the inner surface of the cylindrical member 25; and

5

Blood flow enters the annular radial-flow inlet 23 and is straightened out by the radial blades such as 39 and 40 to finally reach the impeller blades such as 78 and 79.

10

Blood flow then passes through the impeller blades such as 78 and 79, is straightened out by the outflow stator 45 and finally exits through the outflow cannula 42. The radial blades of the stationary outflow stator 45 are shaped and disposed to transform the rotational motion of the blood flow about the longitudinal axis 41 into a translational motion. Therefore, 15 the stationary outflow stator 45 constitutes a blood flow straightener.

20

Still referring to Figure 3, the cylindrical gap 86 separating the impeller shaft 55 and the inner surface of the cylindrical member 25 should be sufficiently thick to produce sufficient blood flow in order to increase washout and prevent clot formation. On the other hand, too large a gap 86 may either reduce the pump efficiency (by reducing the electromagnetic coupling) or result in higher hemolysis.

25

In the illustrative intra-ventricular embodiment of Figures 1 and 3, the volume of blood pumped through the second annular radial-flow inlet 23 is typically 4 liters/minute. This is higher than the volume of blood pumped through the first annular radial-flow inlet 22 and the cylindrical gap 86 which is typically 1 liter/minute. A number of benefits is associated with the 30 higher volume blood pumped through the second inlet 23. For example, installation of the mixed-flow blood pump 2 in the left ventricle 11 of a

patient with the cannula 42 extending through the aortic valve generally interferes with proper operation of the aortic valve. Optimally, the aortic valve should continue to function normally; however, in some cases, it has been observed that the aortic valve ceases to function further until it 5 remains closed around the cannula 42. Typically, blood would have the tendency to collect in the region close to the aortic valve and the cannula 42 which might lead to thrombus formation and other adverse effects. The increased volume of blood pumped through the second inlet 23 has the effect of creating blood flow in the region within the ventricle 11 bordered 10 by the aortic valve and the cannula 42, thus providing improved washout of this region and thereby reducing the effects of the malfunctioning aortic valve.

On the one hand, the volume of blood pumped through the second inlet 23 15 contributes to the radial-flow operation of the mixed-flow blood pump 10. On the other hand, the volume of blood pumped through the first inlet 22 and the cylindrical gap 86 contributes to the axial-flow operation of the mixed-flow blood pump 10.

20 The choice of materials for an implantable device such as the mixed-flow blood pump 10 is crucial and several properties of the available materials should be considered: strength, durability, hardness, elasticity, wear resistance, surface finish and biocompatibility. Biocompatibility is very important to minimise irritation, rejection and thrombogenesis. The 25 interaction between the surface of the material and the biological tissues is very complex. In several cases, treatment of the surface with human proteins, certain drugs like heparin or other biocompatible material may considerably increase the biocompatibility and minimise thrombus formation (CBAS process, Carmeda AB).

30

Figure 6 illustrates an alternative, illustrative extra-ventricular embodiment

101 of mixed-flow blood pump according to the present invention. This  
illustrative embodiment 101 is adapted for use externally of the heart as a  
ventricle bypass/assist. This blood pump 101 would typically be implanted  
above the diaphragm in the thorax and would be connected to the  
5 circulation system using standard vascular grafts, a first graft (not shown)  
being attached to the inflow end 102 of the pump and a second graft (not  
shown) being attached to the outflow end 103 of the pump.

Similar to the mixed-flow blood pump 10 of Figure 3, the alternative  
10 illustrative extra-ventricular embodiment 101 of mixed flow blood pump as  
illustrated in Figure 6 comprises a stationary housing structure 105  
provided with an impeller housing 104.

The stationary housing structure 105 further comprises an outer cylindrical  
15 wall 106 centered on the longitudinal axis 107 of the pump 101. The outer  
cylindrical wall 106 has a proximal end with a reduction of diameter 108 to  
receive the first graft and for connection to the patient's circulation system.  
The outer cylindrical wall 106 further comprises a distal end connected to  
the impeller housing 104.

20 The stationary housing structure 105 of the illustrative extra-ventricular  
embodiment 101 of mixed-flow blood pump according to the present  
invention comprises a hollow cylindrical member 109 containing the stator  
windings such as 110 and the associated magnetic cores such as 111. The  
25 hollow cylindrical member 109 is mounted within the outer cylindrical wall  
106 coaxially therewith to form an annular flow passage 112 between the  
inner surface 113 of the outer cylindrical wall 106 and the outer surface  
114 of the hollow cylindrical member 109.

30 The hollow cylindrical member 109 is made of two mutually mating annular  
pieces 115 and 116 connected together. This will allow insertion of the

stator windings 110 and cores 111 within the hollow cylindrical member 109.

The stationary housing structure 105 further comprises an inflow bushing 5 mount 117 mounted on a proximal end of the cylindrical member 109. More specifically, the bushing mount 117 comprises an annular portion 118 profiled to fit on the proximal end of the hollow cylindrical member 109 while defining with this cylindrical member 109 a smooth surface for the inlet to the annular flow passage 112. An inflow bushing 119 having the 10 general configuration of a frustum of cone is mounted inside the annular portion 118 of the bushing mount 117 and is centered on the longitudinal axis 107 of the blood pump 101. More specifically, the frusto-conical bushing 119 is mounted to the annular portion 118 through a series of radial blades such as 120 and 121 spread out evenly around the 15 longitudinal axis 107, more specifically around the frusto-conical bushing 119. As illustrated in Figure 6, the frusto-conical bushing 119 has an end of larger diameter facing toward the distal end of the pump 101. Again, another function of the blades such as 120 and 121 is to straighten out the 20 flow of blood passing between the frusto-conical bushing 119 and the annular portion 118 of the bushing mount 117.

The distal end of the cylindrical member 25 is connected to the proximal end of the impeller housing 104 through a series of radial blades such as 122 and 123 spread out evenly around the longitudinal axis 107 to define 25 an annular passage between the distal end of the annular flow passage 112 and the proximal end of the impeller blades such as 124 and 125. Another function of the radial blades such as 124 and 125 is to straighten out the flow of blood from the annular flow passage 112.

30 An outflow stator 126 comprises an annular member 127 mounted on the distal end of the impeller housing 38. The outflow stator 126 also

comprises a series of inner radial blades such as 128 and 129 spread out evenly around the longitudinal axis 107. The radial blades such as 128 and 129 are configured to straighten out the flow of blood exiting the outflow stator 126.

5

An outflow bushing 130 having the general configuration of a frustum of cone is mounted inside the outflow stator 128 and is centered on the longitudinal axis 107. More specifically, the frusto-conical bushing 130 is mounted to the radial blades of the outflow stator 128. Finally, the end of 10 larger diameter of the frusto-conical bushing 130 is facing toward the proximal end of the pump 101.

15

A blood diffuser 131 is mounted to the distal end of the outflow stator 126. The function of this blood diffuser 131 is to increase the cross-sectional area of the pump output to the diameter of the second graft while minimising the shear stress on the blood cells. Since the velocity of the blood is inversely proportional to the cross-sectional area, the diffuser 131 will also reduce the velocity of the blood ejected from the pump 101 to a 20 velocity close to that of blood in the patient's circulation system. Of course, parameters such as the angle of opening and the length of the blood diffuser 131 could be adjusted at will to fit the mechanical characteristics of the pump 101 in view of minimising the shear stress on the blood cells.

25

The illustrative, extra-ventricular embodiment 101 of mixed-flow blood pump also comprises an impeller 133 provided with an impeller drive shaft 132 centered on the longitudinal axis 107. The impeller drive shaft 132 comprises an inflow end portion 134 formed with a frusto-conical face 135 structured to snugly fit into the frusto-conical bushing 119.

30

The inner face of the frusto-conical bushing 119 has the same structure and operation as the inner face 47 of the inflow bushing 35 of Figure 3

described in detail with reference to Figure 4.

Still referring to Figure 6, the impeller drive shaft 132 also comprises an outflow portion 136 which, when assembled to the inflow end portion 134 defines a cavity in which a permanent magnet 137 is inserted. The windings 110 and the permanent magnet 137 form an electric motor structure operative to set the impeller 133 into rotation; the magnetic field produced by the windings 110 is applied to the magnetic field produced by the permanent magnet 137 to produce a reaction that will set the impeller 10 133 into rotation.

The above-mentioned 0.8 N axial magnetic pull is produced by slightly offsetting the permanent magnet 137 toward the inflow bushing 119 with respect of the magnetic windings 110. This will produce the 0.8 N axial 15 magnetic pull toward the outflow bushing 130, i.e. in a direction opposite to an axial force produced on the impeller drive shaft 132 upon pumping blood.

An axial screw 138 passes through the magnet 137 and screws into both 20 the inflow 134 and outflow 136 portions of the impeller drive shaft 132 to firmly secure these two drive shaft portions together.

The outflow portion 136 of the impeller drive shaft 132 comprises an outflow end 139 formed with a frusto-conical face 140 structured to snugly 25 fit into the frusto-conical bushing 130.

Again, the inner face of the frusto-conical bushing 130 has the same structure and operation as the inner face 68 of the outflow bushing 46 of Figure 3 described in detail with reference to Figure 5.

30 In the illustrative embodiment of Figure 6, the impeller 133 comprises the

set of impeller blades such as 124 and 125 evenly distributed around a tapered section 141 of the outflow portion 136 of the impeller drive shaft 132 situated inside the impeller housing 104. It should be noted here that the annular flow passage 112 leads through the radial blades such as 122 and 123 to the proximal end of the impeller blades such as 124 and 125. The shape (curvature and angulation) of the impeller blades such as 124 and 125 should be optimally designed in relation to pumping performance and other hydrodynamic considerations. In particular, the influence of the blade angulation on the level of shearing stresses, turbulence and cavitation responsible for red blood cell damage and increase of hemolysis rate must be carefully taken into consideration.

In the approach proposed by the illustrative extra-ventricular embodiment of the present invention, the mixed-flow blood pump 101 presents an enclosed-impeller mixed-flow configuration. The impeller section 141 of the impeller drive shaft 132 bearing the impeller blades such as 124 and 125 is tapered in the direction opposite to the direction of blood flow. This contributes to create the mixed-flow operation of the blood pump 101. More specifically, this taper imparts to the blood flow both axial and radial components.

For housing the impeller blades, the impeller housing 104 comprises an inner surface 142 slightly less tapered in the direction opposite to the direction of blood flow than the section 141. To fit in the annular space defined between tapered section 141 and the tapered surface 142, the height of the impeller blades such as 124 and 125 slightly and gradually decreases in the direction of blood flow. This also contributes to impart to the blood flow both axial and radial components.

30 The end section 143 of the outflow portion 136 of the impeller drive shaft 132 is tapered in the direction of blood flow to fit within the outflow stator

126 and define the frusto-conical face 140. The inner surface 144 of the  
annular member 127 surrounding the end section 143 is slightly less  
tapered in the direction of blood flow than the end section 143 of the  
impeller drive shaft 132. To fit in the annular space between the inner  
5 tapered surface 144 and the end section 143, the radial blades such as  
128 and 129 have a height that slightly and gradually increases in the  
direction of blood flow.

The required electrical supply for the stator windings 110 is made through  
10 electrical wires extending through a conduit 145 itself extending from the  
cavity in which the stator windings 110 are installed through the annular  
piece 116, the radial blade 122, and the impeller housing 104 to reach a  
controller and an energy source (both to be described hereinafter). Of  
course, this conduit 145 is sealed prior to implantation of the pump 101  
15 within a human body.

Electric supply of the stator windings 110 will cause rotation of the impeller  
drive shaft 132 and therefore rotation of the set of impeller blades such as  
124 and 125. More specifically, in the illustrative embodiment of Figure 6,  
20 the mixed-flow blood pump 101 is actuated by means of a brushless DC  
(direct current) motor formed by the stator windings 110 housed in the  
cylindrical member 109 and the permanent magnet 137 embedded or  
housed in the impeller drive shaft 55. This brushless configuration presents  
the advantage of minimal wear. Two other interesting characteristics of  
25 brushless DC motors are high rotational speed and high torque.

Both the annular flow passage 112 and the cylindrical gap 146 between  
the outer surface of the impeller drive shaft 132 and the inner surface of  
the cylindrical member 109 must be both sufficiently thick to produce  
30 sufficient blood flow in order to increase washout and prevent clot  
formation. However, increasing the thickness of the gap 146 decreases the

efficiency of the magnetic coupling between the permanent magnet 137 and the stator windings 110. This requires an increase in current through the stator windings 110 to compensate for the decreased efficiency and to maintain the same characteristics in terms of impeller blade speed and blood volume throughput. Of course, increase in current leads to an increase in thermal loss from the stator windings 110; this thermal loss increases as the square of the current through the stator windings 110. As the temperature of the surface of the stator windings must remain at or below 40°C, the gap 146 must be sufficiently small to provide efficient magnetic coupling between the permanent magnet 137 and the stator windings 110.

Thermal performance is also improved given the proximate position of the stator windings 110 to the annular flow passage 112 and the cylindrical gap 146. Blood flow through these annular flow passage 112 and cylindrical gap 146 efficiently cools the stator windings 110.

Axial spacing between the impeller blades such as 124 and 125 and the permanent magnet 137 along the impeller shaft enables separate design of the motor and the impeller blades to obtain simultaneously both efficient coupling between the permanent magnet and the stator windings and sufficient pumping volume.

Rotation of the impeller blades such as 124 and 125 will impart pumping energy to the blood within the annular space between the tapered section 141 of the drive shaft 132 and the tapered inner surface 142 of the impeller housing 104. This will cause sucking of blood both through the annular flow passage 112 and the cylindrical gap 146. More specifically:

- 30 - Blood flows through the annular flow passage 112 and is straightened out by the radial blades such as 122 and 123 to reach

the impeller blades such as 124 and 125; and

- Blood flow is straightened out by the radial blades such as 120 and 121 to reach the impeller blades such as 124 and 125 through the cylindrical gap 146.

5 Blood flow then passes through the impeller blades such as 124 and 125, is straightened out by the outflow stator blades such as 128 and 129 and finally exits through the blood diffuser 131. The radial blades such as 128 10 and 129 of the stationary outflow stator 126 are shaped and disposed to transform the rotational motion of the blood flow about the longitudinal axis 107 into a translational motion. Therefore, the stationary outflow stator 126 constitutes a blood flow straightener.

15 Again, the choice of materials for an implantable device such as the mixed-flow blood pump 101 is crucial and several properties of the available materials should be considered: strength, durability, hardness, elasticity, wear resistance, surface finish and biocompatibility. Biocompatibility is very important to minimise irritation, rejection and thrombogenesis. The 20 interaction between the surface of the material and the biological tissues is very complex. In several cases, treatment of the surface with human proteins, certain drugs like heparin or other biocompatible material may considerably increase the biocompatibility and minimise thrombus formation.

25 Figure 7 schematically illustrates an embodiment of implantable VAD system including an axial-flow blood pump 10. The VAD system is composed of four main parts:

- 30 - the axial-flow blood pump 10 implanted in the left ventricle 11 of the patient 87;

- an internal controller 88;
  - two energy sources, namely an internal rechargeable battery 89 and an external rechargeable battery 90; and
- 5            - a Transcutaneous Energy and Information Transmission (TEIT) system 91.
- 10          VAD and TEIT Systems are well known in the art and will not be further discussed in the present specification.

To conclude, ventricular assist devices (VADs) are now being used worldwide and their utilisation is becoming more and more accepted as a solution to treat end stage heart failure. It is generally accepted that VADs extend life of patients while improving quality of life of these patients. A poll, made with patients who received VADs, concerning their quality of life revealed that these patients would have preferred a heart transplant but prefer their situation than having to be on dialyses.

20          It is also now being accepted that VAD is becoming a cost effective solution considering the fact that patients are discharged from the hospitals more rapidly and may return to normal life occupations. In the United States, several insurance companies are now reimbursing the implantation  
25          of VADs.

Finally, the mixed-flow blood pump 10 according to the illustrative embodiments of the present invention provides an excellent bridge to heart transplant and aims at long term implant. The new proposed mixed-flow blood pump 10 should answer most of the remaining problems and limitations of the prior axial-flow blood pumps, especially those related to

- hemolysis. Hemolysis is the tearing of red blood cells, which empties the content of the cells in the blood stream resulting in free haemoglobin; the normal level of plasma free haemoglobin is around 10 mg/dl. A blood pump with a normalised index of hemolysis (NIH) of 0.005 g/100 litres and lower is considered to be almost atrumatic for red blood cells. A NIH of about 0.05 g/100 litres could be tolerated. A NIH situated between 0.005 g/100 litres to 0.05 g/100 litres can therefore be envisaged for a VAD. Of course, a NIH as close to 0.005 g/100 litres as possible is desirable.
- 5
- 10 Although the present invention has been described hereinabove by way of illustrative embodiments thereof, these embodiments can be modified at will, within the scope of the appended claims, without departing from the spirit and nature of the present invention.

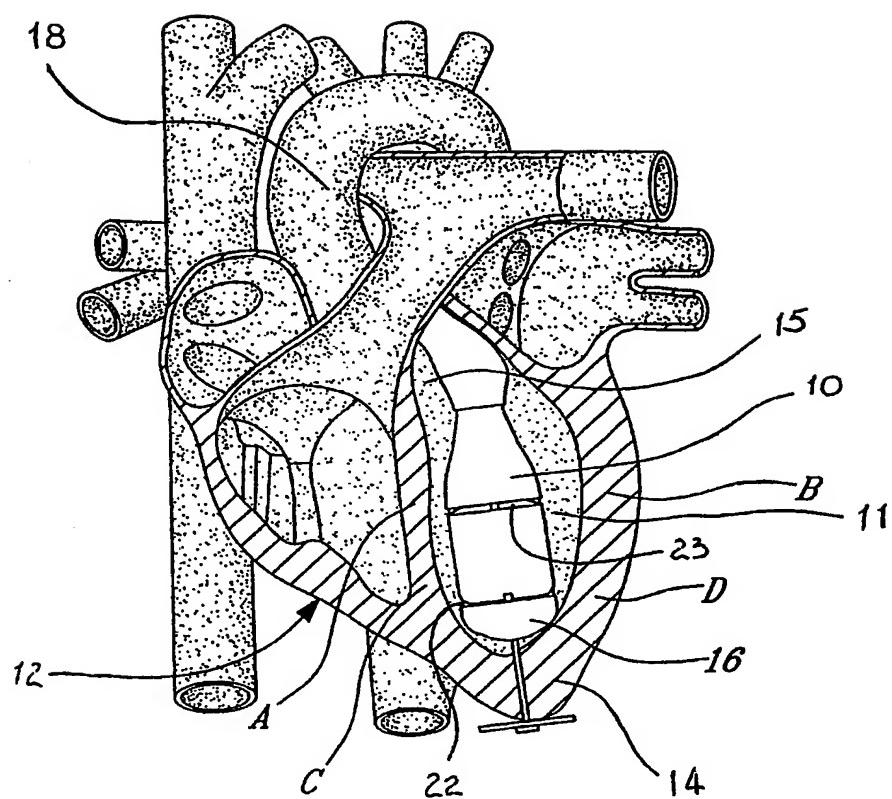


FIGURE - 1

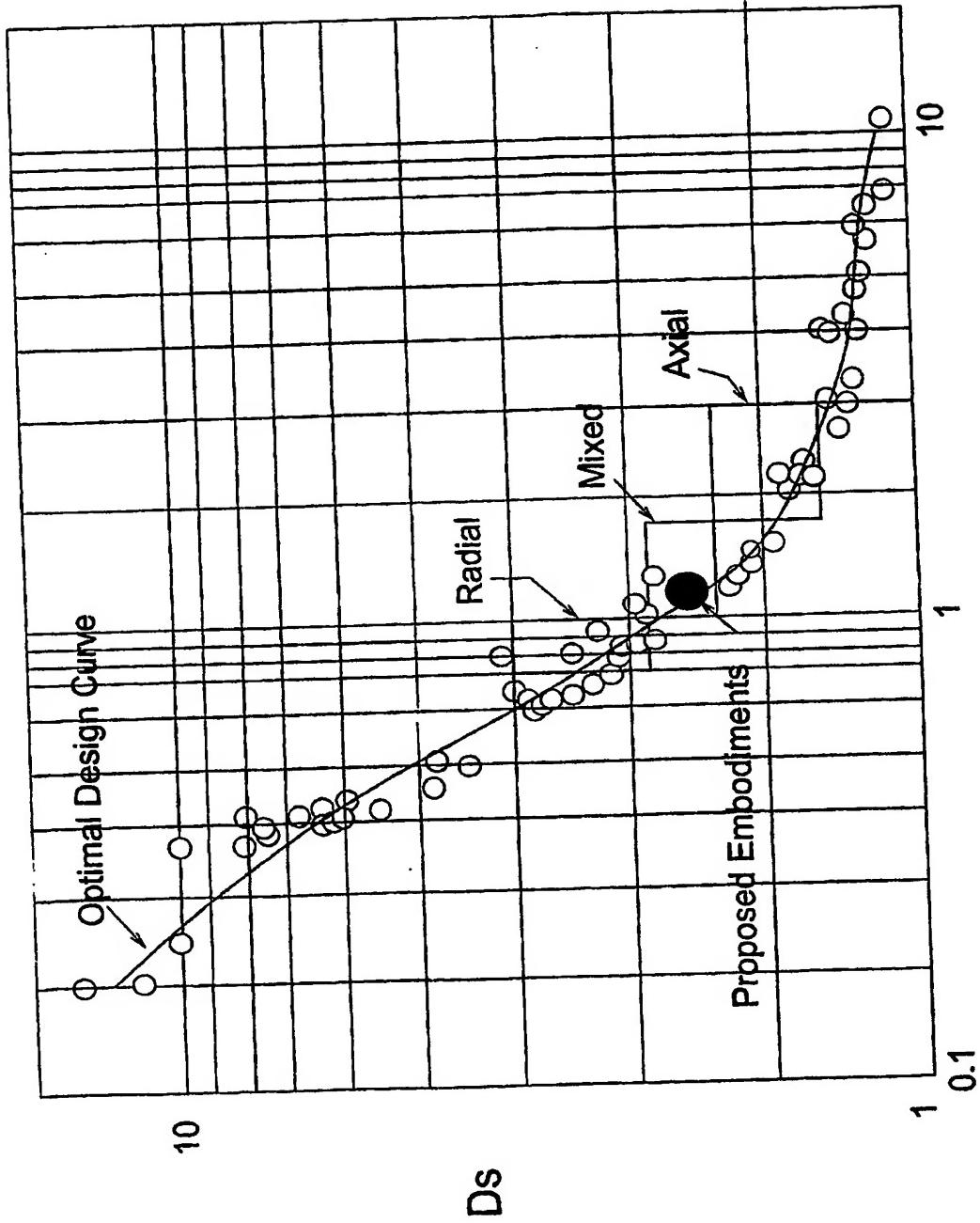


FIG:2

Ns

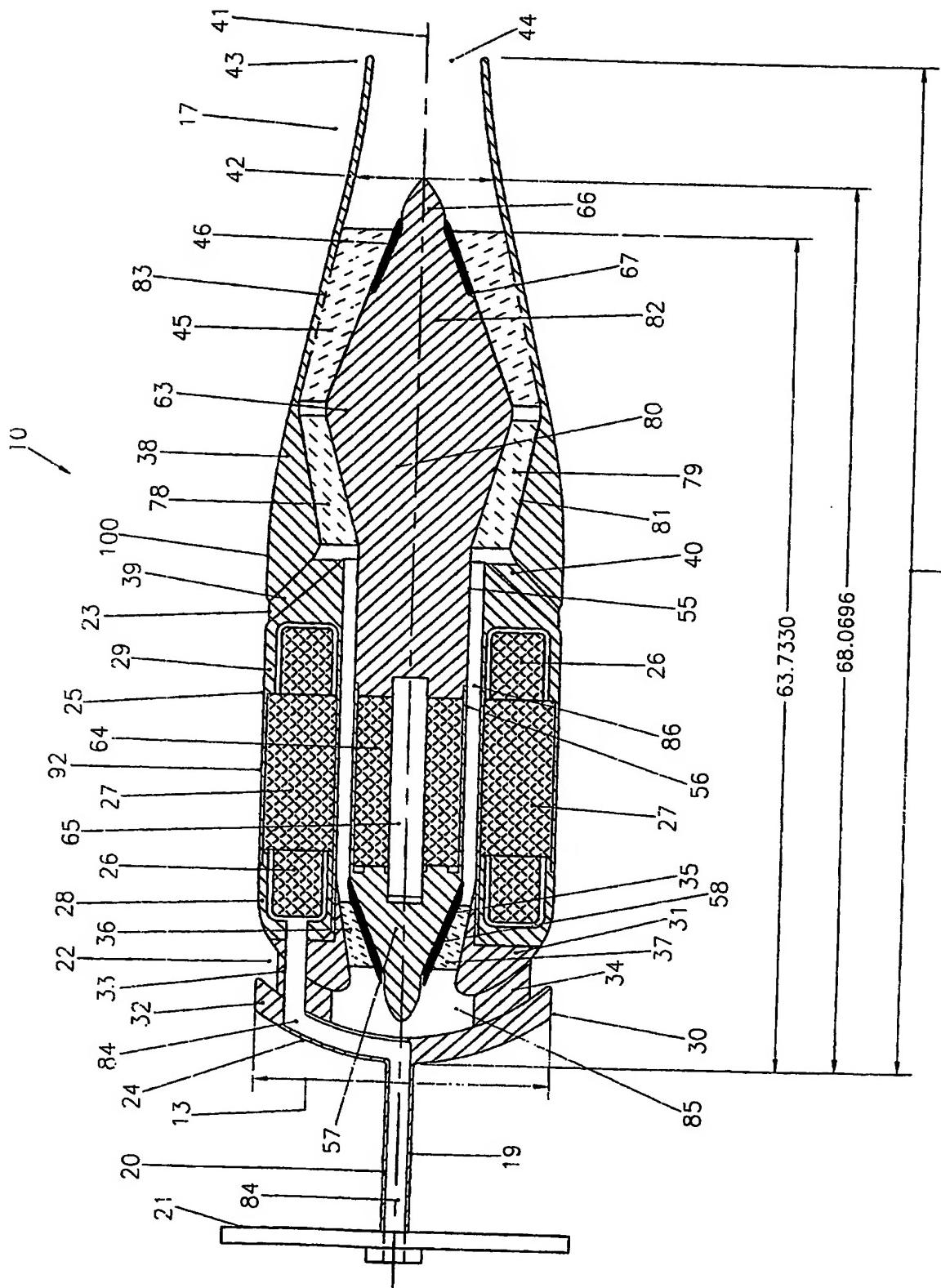


FIG:3

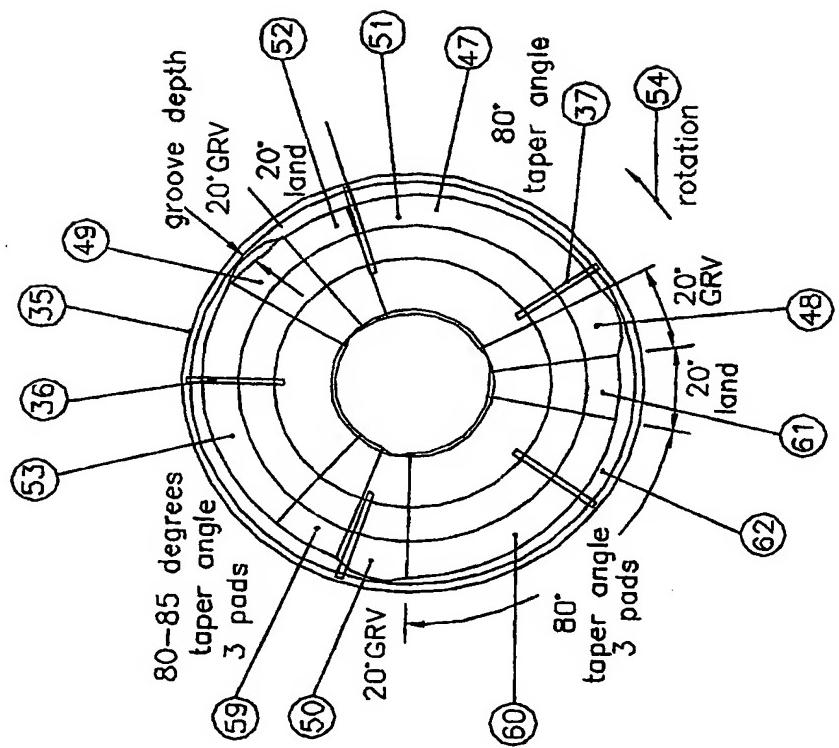


FIG: 4

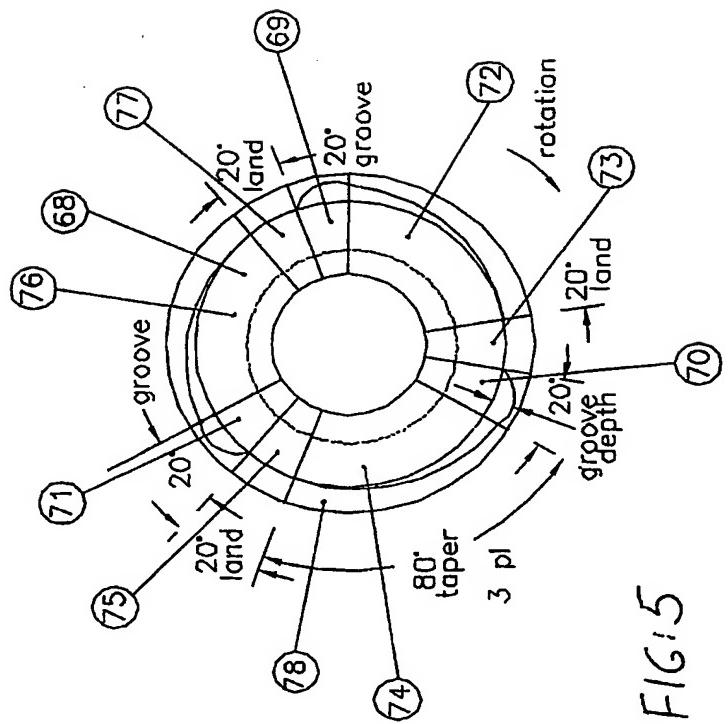
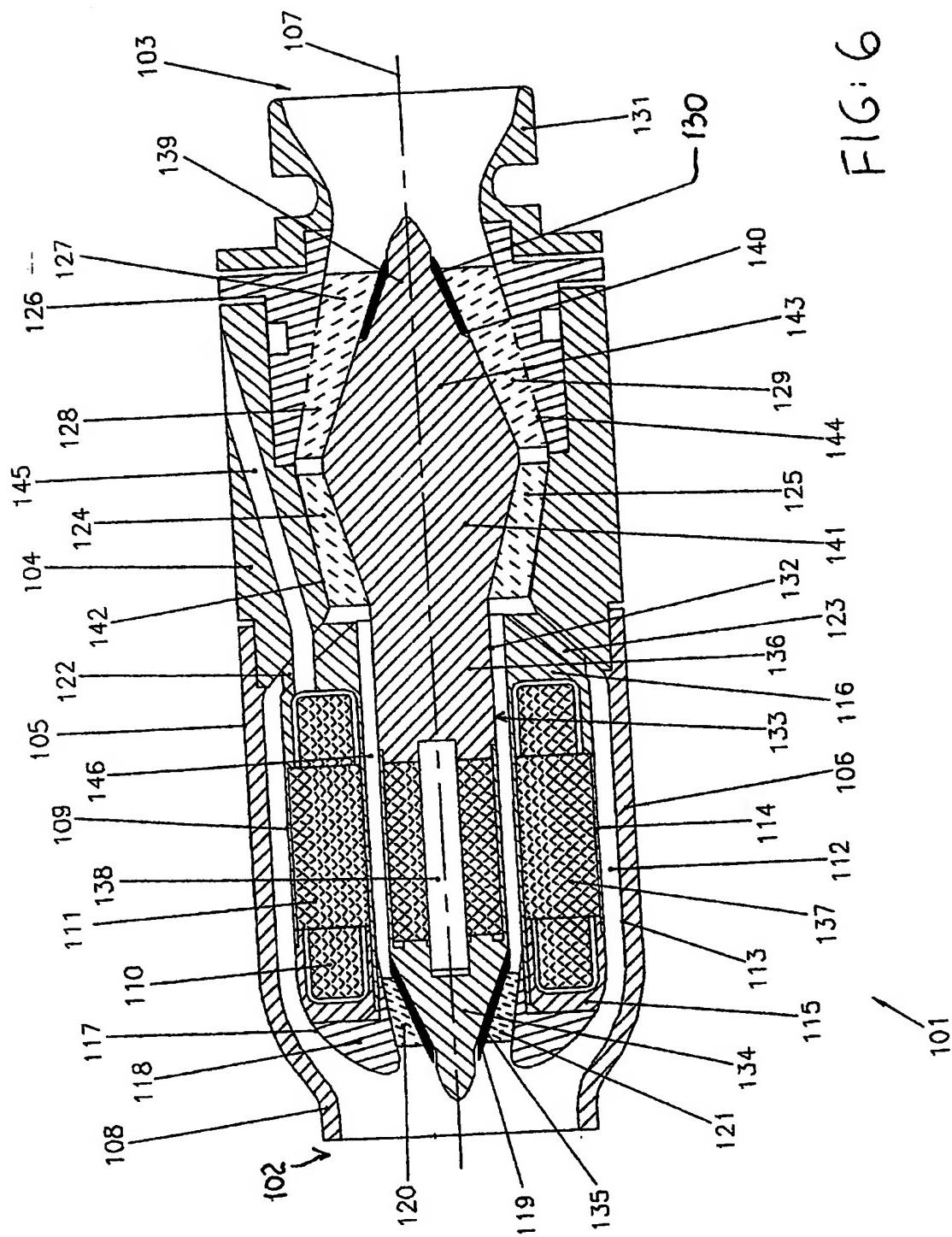
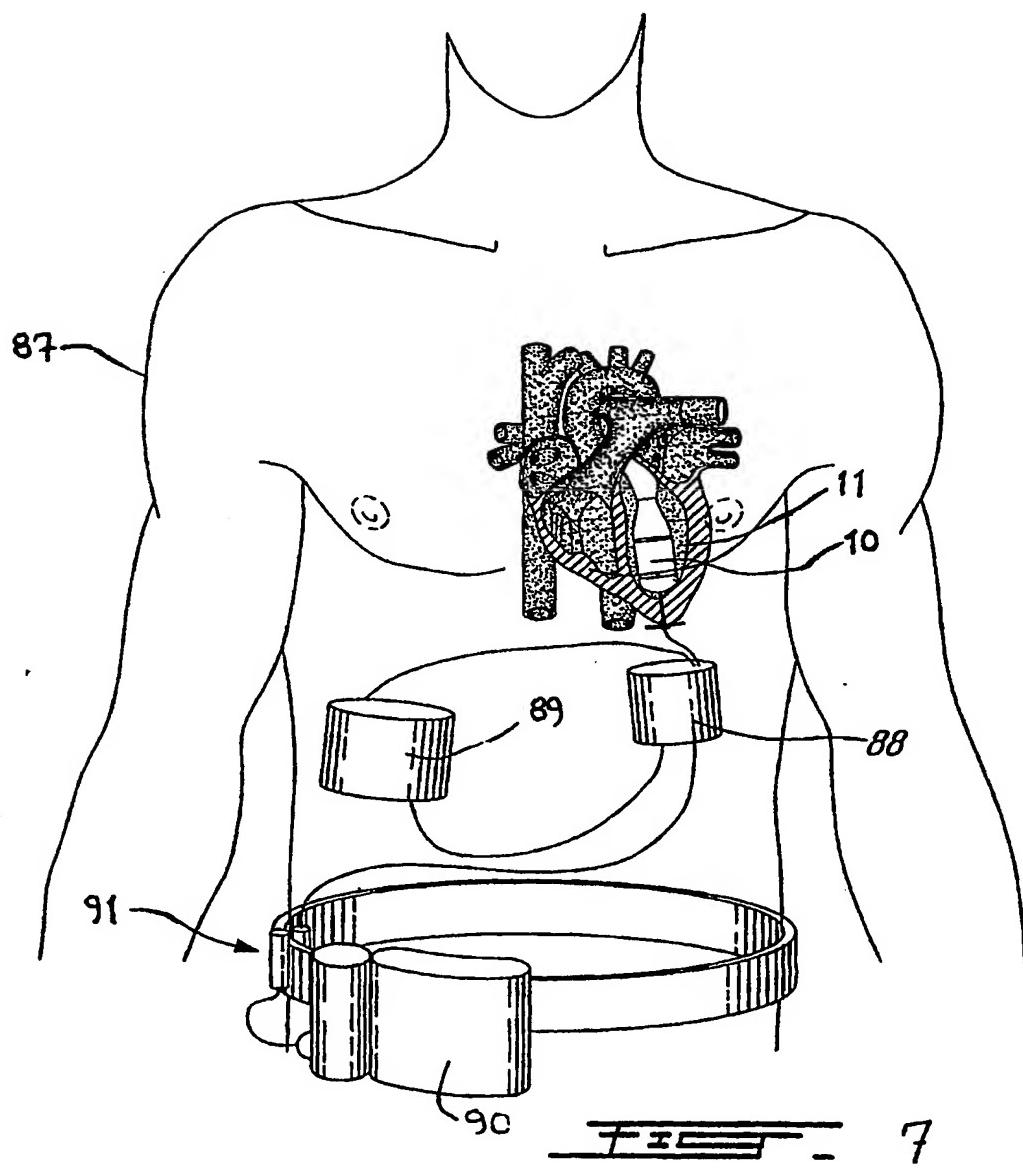


FIG. 5





**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

**BLACK BORDERS**

**IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**

**FADED TEXT OR DRAWING**

**BLURRED OR ILLEGIBLE TEXT OR DRAWING**

**SKEWED/SLANTED IMAGES**

**COLOR OR BLACK AND WHITE PHOTOGRAPHS**

**GRAY SCALE DOCUMENTS**

**LINES OR MARKS ON ORIGINAL DOCUMENT**

**REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

**OTHER:** \_\_\_\_\_

## **IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**